



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/649,974

08/27/2003

Joseph Senesac

29853/37704A

7068

4743

7590

08/21/2008

MARSHALL, GERSTEIN & BORUN LLP
233 S. WACKER DRIVE, SUITE 6300
SEARS TOWER
CHICAGO, IL 60606

EXAMINER

LANKFORD JR, LEON B

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

08/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/649,974	Applicant(s) SENESAC, JOSEPH	
	Examiner Leon B. Lankford	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 70-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/21/08 & 2/14/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-69 remain rejected under 35 U.S.C: 103(a) as being unpatentable over Huyghe et al (Hum Gen Ther 6:1403-1416 (1995)).

The claims remain rejected for the reasons of record.

Applicant's arguments filed 3/24/08 have been fully considered but they are not persuasive.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Applicant must discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

The applicant has argued that the rejection fails to teach or suggest all the elements of the claimed invention but fails to point out specific failings noting only that there is "no teaching or suggestion concerning the use of dye affinity media for the purification of adenovirus" or "heparin affinity media"(response pages 16-17). It would appear that applicant is alleging only the patentability of claim 6 and thereby conceding that the broader claims are obvious but the examiner will address the response as it pertains to all claims. Applicant has claimed their invention as if it is a broadly patentable method and the examiner has rejected the claims accordingly. No election of species was required because the media used are all old and notoriously well known. Applicant claims a method of combining known chromatographic techniques to isolate a known virus that has been previously isolated using a variety of chromatographic media. While it may be the case that there is a particular combination of methods that yields an unobvious result, applicant has made no such argument.

Applicant's arguments have been considered however a showing to overcome a prima facie case of obviousness must be clear and convincing(In re Lohr et al. 137 USPQ 548) as well as commensurate in scope with the claimed subject matter (In re

Lindner 173 USPQ 356; In re Hyson, 172 USPQ 399 and In re Boesch et al., 205 USPQ 215 (CCPA 1980). Applicant has not specifically argued the use of any particular combination chromatographic media will be unobvious and as such applicant's claimed invention is deemed obvious at the time the invention was made.

Applicant should recognize that the rationale supporting a rejection Under 35 USC 103 may in addition to being in the reference, be reasoned from common knowledge in the art, scientific principles, art-recognized equivalents or legal precedent. Applicant is suggested to read section 2144 of the MPEP.

Even if applicant were to argue the unobvious use of specific media, it is suggested that absent a showing of a particularly advantageous combination, the selection of a particular medium would appear to be a matter of substitution of art-recognized equivalents and as such *prima facie* obvious.

It is also well established that it is obvious to combine known things for their anticipated result. Applicant would appear to suggest that using known purification techniques in combination would not be expected to yield a purer product. It is old and notoriously well known in the chromatographic art to duplicate a chromatographic purification or sequence diverse protocols until the desired purity is achieved. It would not appear feasible that applicant is arguing that one of ordinary skill in the art would know that different chromatographic materials will serve to eliminate different impurities or undesirable components from a mixture and as such aiding in the purification of the desired component- in the instant case that would be adenovirus.

It is the examiner's opinion that the sections of *KSR* cited by applicant do not suggest that the instant invention would not have been obvious at the time the invention was made but, in fact, in context with the whole decision (or even just the parts previously referenced by the examiner), would lead one of ordinary skill in the art to find the claimed invention obvious in view of the prior art. The prior art teaches the chromatographic purification of adenovirus with diverse media and as such is sufficient to suggest that combinations of chromatographic media could be used to isolate the virus. The number of known types of media is a finite consideration and the results of using the media in sequence would have been anticipated to be further purification of the virus.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date

of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon B. Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651